Department of Pesticide Regulation

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Friends:

As part of our report on long-term, stable funding (Assembly Bill 780), the California Legislature requested that we address potential improvements in the efficiency of the Department of Pesticide Regulation's operations, including mechanisms to share pesticide registration workload with the U.S. Environmental Protection Agency.

During development of the report, we worked with representatives from organizations interested in improving the Department of Pesticide Regulation's operations, particularly the registration process. As a result of these discussions, we produced a summary of key issues that are repeatedly raised about the registration process (copy attached). Please feel free to distribute this information to any interested parties.

Thank you,

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Attachment

Department of Pesticide Regulation
Pesticide Product Registration
Perceived Duplication with U.S. Environmental Protection Agency
Efficiencies and Resources
January 2003

The pesticide product registration function is one of the major business operations of the Department of Regulation (DPR). As we face the fiscal challenges and establish long term stable funding, several issues concerning pesticide product registration arise:

Is there duplication with the U.S. Environmental Protection Agency (U.S. EPA)?
How can U.S. EPA and DPR share the work?
Has DPR made the registration process efficient?

In regards to perceived duplication with U.S. EPA, a review of the two programs found little duplication. Although both agencies register pesticide products, the laws are different:

- DPR's review focuses on California-specific impacts.
- DPR has authority to waive submission of some studies, and often conditionally registers while studies are completed.
- U.S. EPA allows an applicant for registrations of a pesticide product containing the same active ingredient as products already registered (even though the formulation may not be the same) to skip data submission and review, and simply cite "all" data on file with U.S. EPA, without identifying specific studies or whether the studies are relevant to the product's formulation.
- California may require additional studies such as data on worker exposure, foliar residue, indoor exposure potential, hazards to bees, dust hazard of powdered products to workers, and efficacy.

Even with the statutory differences, we have found many areas in which to improve our processes and work together. We found that sharing the work may not always take less resources, but can result in reaching a registration decision faster. During the past five years, we've seen increasingly successful DPR and U.S. EPA efforts to collaborate and cooperate on exchanging information and data reviews. We are maximizing scarce resources and emphasizing areas of focus and expertise. Our efforts have moved from a manager-to-manager level to a scientist-to-scientist level, which has greatly enhanced the exchange of information and work products. In the past two years, DPR's reviews of residue data have expedited federal registration of 15 pesticides on 85 California commodities that represent more than $6.6 billion to the state's farm economy. Expansion to dietary assessment will be our next area.

Bringing pesticide products to the marketplace as quickly as possible, especially those posing a lower risk, is one of DPR's goals. One way to accomplish this goal is to reduce the lag-time between federal and state registration. To reach this goal, DPR has enacted numerous reforms to streamline our registration process. The following sections are

extracted from the AB 780 report, and cover in more detail the specifics of state and federal pesticide registration requirements, as well as our efforts to improve our registration program.

Details: State/Federal Pesticide Product Registration

Periodically in the past 20 years, industry stakeholders have mistakenly perceived California's pesticide regulatory program to be duplicative of other government programs. In 1990, an outbreak of this criticism during mill reauthorization hearings prompted the Legislature to require a report evaluating regulatory program elements funded with the mill assessment "to determine which program components can be modified or eliminated in order to avoid duplication of any other State or federal requirements."

One particular focus of industry stakeholders has been California's pesticide registration program, unique in the nation for the breadth and depth of its evaluation of pesticides before they can be offered for sale in the state. On the surface, the criticism is understandable as both DPR and U.S. EPA evaluate and license pesticides for sale and use. However, while there are similarities, there are significant differences between the laws and regulations that govern operations at the State and federal level, not the least of which is the CEQA requirement that California agencies, including DPR, consider the impact of a permit on California's environment. That this criticism continues to resurface owes much to a lack of understanding of the inherent differences between federal and California laws, as well as to a lack of knowledge of the progress that DPR has made in eliminating unnecessary redundancies and in increasing programmatic efficiency. This criticism also does not recognize the statutorily mandated higher expectations that the citizens of California (including State legislators) have regarding worker and public safety and California's environment.

Charges of programmatic redundancies surface at the federal level as well. Those who register and distribute pesticides regularly complain to Congress that–given federal standards–local and state pesticide use restrictions are unnecessary and make it difficult to conduct business from state to state. However, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA, the omnibus federal pesticide statute) *specifically* authorizes state regulation of the sale and use of federally registered pesticides as long as state regulations are at least as restrictive as federal standards. Under FIFRA, for example, states may prohibit the distribution and sale of a federally registered pesticide or restrict pesticide use locally to protect groundwater, wildlife, or human health. (Acknowledging the realities of interstate commerce, FIFRA does prohibit states from imposing their own requirements on pesticide labeling or packaging.)

The pivotal role of the states in regulating the use of pesticides is a result of lobbying by the states, which argued successfully that their level of control is more knowledgeable, precise, and reliable. The federal role, by design, is not intended to substitute for the authority of any state to pursue a regulatory approach best suited to local conditions. This perspective was restated during the 1996 U.S. Senate debate on FIFRA

amendments, summarized in a bill analysis by Senate staff: "Throughout history, States traditionally have had the fundamental responsibility of protecting health and safety. Over time, as some health and safety issues have become more complex and national in scope, some of these responsibilities have been shifted to the federal government. In general, federal authority has not increased at the expense of State authority. Even when it has, existing statutes have allowed States to set more stringent standards than federal standards, if so desired and needed. We should permit States to set separate safety standards. States can set these standards more quickly than the U.S. EPA in response to an emergency. They can also set a standard that provides more comprehensive protection than a federal standard. Some states, for example, have formulated standards that are more stringent than federal standards and are better designed to protect individual groups of citizens. If states are no longer able to act independently to protect health, they will lose their access to the federal process, and the balance of the current system will be lost. It remains a question of policy, of wise interpretation of the Constitution, which recognizes that the federal government should not move in with a heavy foot and stomp on the rights of individual states to pass judgment on products that have a direct effect on the health and safety of their citizens."

While there are similarities in U.S. EPA's and DPR's pesticide regulatory programs, there are significant differences as well. For example, DPR and U.S. EPA may review some of the same studies submitted with an application for registration, but may rely on different studies to reach a registration conclusion; in some cases, the conclusions differ, in part because DPR focuses on California-specific impacts. DPR may refuse to register a product because of potential impacts on workers in California's labor-intensive agriculture, or because the only use of the product in California would be in an area that is also home to an endangered species that could be harmed by the pesticide.

Under federal regulations, applicants for U.S. EPA registration of a pesticide product containing the same active ingredient as products already registered (even though the formulation may not be the same) are not required to submit data, and can instead simply cite "all" data on file with U.S. EPA that was previously submitted by other registrants. U.S. EPA does not determine whether relevant studies are on file to support all registered pesticide products until some later date when the active ingredient goes through the federal reregistration process. On the other hand, applicants for California registration of a new pesticide product must either submit all required data, or specifically cite relevant data currently on file with DPR. If the applicant does not own the cited data, they must obtain a letter of authorization from the data owner. Also, DPR may require additional or different studies that were not required by U.S. EPA for federal registration of a specific product. These additional studies may include, but are not limited to, data on worker exposure, foliar residue, indoor exposure potential, hazards to bees, and dust hazard of powdered products to workers.

Additionally, DPR requires that efficacy data be submitted with all applications for registration. U.S. EPA requires that manufacturers develop but not necessarily submit such data, except for products that have public health impacts such as disinfectants.

DPR's evaluation of product effectiveness data protects California pesticide users from the consequences of ineffective products.

There are also significant differences between U.S. EPA and DPR in how data are considered. California agriculture differs from the field crops of the Midwest and South (corn, soybeans, and cotton, for example) that, because of their extensive national acreage, are the primary focus of U.S. EPA. California agriculture is irrigated, changing how pesticides are applied and how workers—irrigators moving pipe, for example—may be exposed. Field crops, moreover, require little cultural care during the growing season and are primarily harvested mechanically, by workers driving in enclosed cabs. California's many and varied fruit, nut and vegetable crops often require extensive cultural care before harvest, with accompanying worker contact with foliage, and many are hand-harvested.

DPR gives special attention to use under California climatic and cultural conditions. Studies have demonstrated that pesticide residues that may decay rapidly under warm, humid conditions may persist longer under hot, dry conditions typical of many California agricultural areas. Some crops, such as rice, may be grown with different water and land management practices in California than in other areas of the country. Algaecides and other pesticides used in swimming pools must reflect the outdoor, year-round use that is typical in California. These and other differences affect the evaluation of safety and effectiveness of pesticide products in California. DPR has expertise in evaluating California-specific impacts on the environment and health that U.S.EPA–with its nationwide scope–cannot have.

DPR on occasion denies registration of products that have obtained federal registration. These denials have been based on such factors as a lack of appropriate or adequate studies required by DPR, label instructions that do not provide sufficient mitigation of product hazard, and an insufficient margin of safety in the projected use. As a result of registration review, the Department also may impose use restrictions and mitigation measures in addition to those on pesticide labels, assuring that valuable pest control technologies are made available to California consumers while potential risks to the public, workers, and/or the environment are minimized.

Risk-Benefit Considerations: Another difference between the U.S. EPA and DPR registration process is that FIFRA requires U.S. EPA to balance risk considerations with economic benefits. During the registration process and more formally, during cancellation proceedings, U.S. EPA must determine not only whether there are "unreasonable adverse effects on the environment," but must also take into consideration the "economic, social, and environmental costs and benefits of the use of any pesticide." In a suspension proceeding, U.S. EPA is not required to balance environmental risks and benefits, although it has been U.S. EPA's policy to conduct such an analysis.

The differences between federal and state laws in this regard are subtle but critical. U.S. EPA is charged by FIFRA to register a pesticide upon determining that: "[I]ts composition is such as to warrant the proposed claims for it; its labeling and other

material required to be submitted comply with the requirements of FIFRA; it will perform its intended function without unreasonable adverse effects on the environment; and, when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment." (FIFRA, section 3[c][5]). Although the risk-benefit provisions of FIFRA were modified in 1996 to ensure health-based safety standards for dietary residues, federal law mandates U.S. EPA consider economic benefits of pesticides. FIFRA section 2(bb) defines "unreasonable adverse effects on the environment" to mean "(1) any unreasonable risk to man or to the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the Federal Food, Drug and Cosmetic Act . . ." Similarly, U.S. EPA may cancel the registration of a pesticide if it finds that: "[W]hen used in accordance with widespread and commonly recognized practice, [it] generally causes unreasonable adverse effects on the environment." (FIFRA, section 6[b]).

California law does not require consideration of economic benefits and DPR does not register products with unmitigated, significant adverse effects, no matter the benefit. California law provides a clear mandate to assure that pesticide use in the state poses as little risk as possible to the public, farm workers, and the State's environment. The basic decision rule is simple: DPR may approve a pesticide registration application (and, if already registered, allow continued use) if it is convinced that the pesticide can be used safely, assuming the product is applied according to label directions, and in accordance with any additional permitting requirements DPR might implement under certain circumstances. Food and Agricultural Code section 12824 requires DPR to "[T]he director shall endeavor to eliminate from use in the state any pesticide which endangers the agricultural or non-agricultural environment, is not beneficial for the purposes for which it is sold, or is misrepresented."

Details: Harmonization/Worksharing

While criticism of redundancy greatly overstates the case, and critical differences in law and methodology exist between U.S. EPA and DPR, there is nonetheless ample room for cooperation and coordination. Over the past decade, the two agencies have made significant strides in worksharing as they explore their respective procedures, methods, and areas of special expertise. However, DPR will continue to focus on areas of interest to California: that is, the State's particular mix of food and fiber crops, and more broadly, the unique concerns of California residents, particularly at the agricultural-urban interface.

U.S. EPA, in turn, has its own focus areas, in particular, cumulative risks posed by pesticides with common mechanisms of toxicity; endocrine disruptor screening and testing; identifying and developing new methods for complex ecological risk assessments; advancing the use of safer inert ingredients; and tolerance reassessment mandated by the federal Food Quality Protection Act (FQPA). U.S. EPA also has made extensive use of California data gathered by DPR as it carries out the mandates of FQPA.

California pesticide use reporting data has assisted U.S. EPA by providing percent-of-crop-treated information necessary so as not to overstate cumulative risk. Moreover, U.S. EPA has acknowledged the high level of expertise and professionalism of DPR scientific staff by appointing a number of them to various panels that advise the federal agency on scientific policy and methodology. This also helps ensure that California's concerns are recognized in the formation of federal scientific policies, and at that same time, that DPR policy development is informed by actions at the federal level.

Harmonization to Worksharing with U.S. EPA: The efforts to improve the state and federal registration process began in the early 1990s through what was then called a "harmonization" project. The initial approach was to bridge the methodologies that the two agencies use in reviewing registration actions. Beyond reaching agreement on acute toxicity reviews, the effort failed to produce notable gains. However, one aspect that showed promise was collaborating on specific product registrations, particularly at the staff level. Beginning in 1999, DPR and U.S. EPA began a more formal partnership to share the workload involved in establishing permanent and time-limited residue tolerances for California's fruit, vegetable, and nut crops. This workshare project uses data from IR-4, a U.S. Department of Agriculture program that provides pesticide residue data for fruit, vegetable, and nut crops. The work in reviewing data and developing many of the scientific evaluations necessary to support tolerances begins in California and is completed at U.S. EPA, each agency focusing on their areas of expertise, achieving efficiencies based on operational transparency, cooperation and collaboration.

Details: Eliminating Unnecessary Redundancies and Improving Efficiency

We have pursued an aggressive effort to work cooperatively with U.S. EPA, avoiding duplication of effort and developing specialized expertise tailored to augment and complement U.S. EPA. Additionally, we have actively pursued an ambitious agenda of self-examination to achieve maximum efficiencies, reduce duplication, and provide better service to the public and to regulated industries. Laws enacted in the early 1990s (SB 1082, 1993, and AB 2711, 1994) institutionalized continuous improvement in State government. Since the Department was created in 1991, highlights include:

- Appointment of a Pesticide Registration Ombudsman.
- Conducting training sessions for registrants.
- Implementing legislation that helps expedite registration of products that fit into pest management systems (AB 771).
- Workshare programs.

Registration Business Processes: The process of evaluating and registering pesticide products is particularly complex, involving interaction of several DPR branches and hundreds of stakeholders. This core business activity is therefore a natural focus of process improvement efforts.

- *Concurrent application for registration:* No pesticide can be offered for sale to persons in California without registration from both U.S. EPA and DPR. (The exception is a class of compounds known as adjuvants. These products–spray adjuvants, emulsifiers, spreaders, and similar compounds that enhance the effectiveness of pesticides–must be registered in California but are exempt from federal registration requirements.)

  Until the mid-1990s, the time lag between federal and state registration actions might have been several months to two years or more. DPR responded by allowing persons to apply for California registration of certain pesticide products concurrently with their application to U.S. EPA. In 1994, DPR began accepting concurrent applications for registration of biochemical and microbial pesticide products, and those formally designated "reduced-risk" by U.S. EPA. In 1999, DPR added antimicrobial and public health protection products for concurrent application. These changes doubled the number of submissions to the Department, and in the 1999-2000 fiscal year, the Legislature provided additional staffing and resources to handle the added workload. However, expanding the categories of applications accepted for concurrent review did not inherently enhance efficiency. This required expanding and enhancing worksharing efforts between DPR and U.S. EPA that, beginning in 1998, established a framework for both agencies to improve the efficiency of their registration processes. (Budget shortfalls in the 2002-03 fiscal year forced the Department to suspend concurrent review of applications for U.S. EPA-designated reduced-risk products. The Department is still accepting concurrent applications for biochemical, microbial, antimicrobial, and public health protection products.)

- *Removing Bureaucratic Obstacles:* In 1996, DPR instituted a notification-only process similar to one in place at U.S. EPA. This process allows registrants making certain minor revisions to their product labels to simply notify DPR of the changes, bypassing the sometimes cumbersome label amendment process. In 1999, DPR reduced data requirements for certain low-risk pheromone products. In 2000, DPR put its *Registration Desk Manual* online to assist applicants and others in understanding California's pesticide registration process. The manual, which is a reference guide for DPR staff, describes different types of registrations, general data requirements, the various scientific evaluation stations, and other steps in the pesticide registration process.

  Also in 2000, DPR formed a Business Process Workgroup with key registrants–the people who bring pesticides to market in California–to exchange ideas for using information technology to improve how DPR conducts business. Its goal is to make the registration process and Department priorities and decisions more transparent. In 2000, DPR adopted regulations exempting certain kinds of minimum-risk pesticides from registration requirements, paralleling an earlier U.S. EPA action. Most exempt chemicals are low-risk substances that have a wide range of other, nonpesticidal uses as foods, medicines, or household items.

- *Using Information Technology to Improve Registration Processes:* In the mid-1990s, DPR's Pesticide Registration Branch developed Web-based access to the Department's product/label database, and established the only free online access to U.S. EPA's database of registered products. From 1997 through 2000, the Branch moved aggressively to use information technology to enhance operations. Accomplishments included significant improvements to the product licensing and renewal, document intake, chemical information, data index, and pesticide data circulation systems. The new systems provide better internal access and reporting capabilities, and streamline operations. In 1999, a Web-based tracking system for the 6,000-plus pesticide registration actions that DPR handles yearly was developed and installed on DPR's internal Home Page. By mid-2003, the Registration Branch intends to launch a program to automatically notify registrants of the review status of their applications for registration. Movement of an application in the registration process will automatically trigger e-mail messages to applicants detailing the status of their applications.